

## **REMARKS**

This amendment is in reply to the final Office Action mailed December 2, 2004. Claims 142, 144 and 146 had been cancelled without prejudice in the previous amendment and response filed July 12, 2004, in reply to the Office Action mailed March 10, 2004. Thus, Applicants believe that Claims 122-141, 143, 145 and 147-149 were pending in the instant Application. In this amendment, Claims 132, 133, 149 and 150 have been cancelled without prejudice. Claims 122-124, 126-131, 134, 136-141, 143, 145 and 148 have been amended, and Claims 151-211 have been added. Therefore, after entry of the instant amendment, Claims 122-131, 134-141, 143, 145, 147-148 and 151-211 will be pending and under consideration.

Applicants believe that entry of the amendment to the claims is proper under 37 C.F.R. § 1.116 because the amendment is believed to place the claims in condition for allowance. Applicants note that, although a number of new claims are added in the present amendment, the subject matter of the new claims had been examined in the previously pending claims, and no new search is required to examine the new claims. In particular, the new claims relate to, *inter alia*, the effects of mutations in codon 90 of HIV protease in combination with certain other HIV protease mutations. Such combinations of mutations were previously recited by the pending claims, and thus Applicants believe that no new search is required for examination of the new claims.

### **I. Interview Summary**

Pursuant to 37 C.F.R. § 1.133 and M.P.E.P. 713.04, Applicants present this interview Summary Record of the telephonic interview of January 18, 2005 between Examiner Shanon Foley and Applicants' representatives, Nikolaos George and David Pauling, in connection with the above-referenced application. At the outset, Applicants would like to thank Examiner Shanon Foley for the courtesies extended during the telephone interview. During the telephonic interview, the pending claims and the prior art reference Craig *et al.*, 1998, *AIDS*. 12:1611-1618 ("Craig *et al.*") were discussed. Specifically, proposed language to overcome the rejection under 35 U.S.C. § 112, second paragraph and Table 2 of Craig *et al.* in view of Claims 122-126 were discussed.

Examiner Foley agreed to consider the amendments and arguments presented in this paper. Applicants respectfully request entry of the foregoing remarks into the file history of the above-identified application.

## **II. The Amendment to the Claims**

### **A. The Amendment to Claims 132, 133, 149 and 150**

In the instant amendment, Claims 132, 133, 149 and 150 have been cancelled without prejudice to Applicants' right to pursue the subject matter of the cancelled claims in one or more related continuation, divisional, or continuation-in-part application(s).

### **B. The Amendment to Claims 122-124, 126-131, 134, 136-141, 143, 145 and 148**

Claims 122-124, 126-131, 134, 136-141, 143, 145 and 148 have been amended. The amendments to Claims 122-124, 126-134, 136-141, 143, 145 and 148 are fully supported by the specification and claims of the application as originally filed.

In particular, support for the amendment to Claim 122 can be found, for example, in Claims 98 and 100 as originally filed and in the specification at page 60, lines 1-17. Support for the amendment to Claim 123 can be found, for example, in Claim 99 as originally filed and in the specification at page 60, lines 18-23. Support for the amendment to Claim 124 can be found, for example, in Claim 107 as originally filed and at page 164, line 28 to page 165, line 3.

Support for the amendment to Claim 126 can be found, for example, in Claim 117 as originally filed and in the specification at page 167, lines 11-28. Support for the amendment to Claim 127 can be found, for example, in Claim 98 as originally filed and in the specification at page 60, lines 1-17. Support for the amendment to Claim 128 can be found, for example, in Claim 99 as originally filed and in the specification at page 60, lines 18-23. Support for the amendment to Claim 129 can be found, for example, in Claim 100 as originally filed and in the specification at page 60, lines 25-29. Support for the amendment to Claim 130 can be found, for example, in Claim 101 as originally filed and in the specification at page 163, lines 2-19. Support for the amendment to Claim 131 can be found, for example, in Claim 102 as originally filed and in the specification at page 163, lines 21-29. Support for the amendment to Claim 134 can be found, for example, in Claim 107 as originally filed and in the specification at page 164, line 28, to page 165, line 3. Support for the amendment to Claim 136 can be found, for example, in Claim 110 as originally filed and in the specification at page 165, lines 17-25. Support for the amendment to Claim 137 can be found, for example, in Claim 112 as originally filed and in the specification at page 166, lines 1-10.

Support for the amendment to Claim 138 can be found, for example, in Claim 199 as originally filed and in the specification at page 168, lines 5-15. Support for the amendment to

Claim 139 can be found, for example, in Claims 103, 106, 111, and 120 as originally filed and in the specification at page 163, line 31 to page 164, line 4, at page 164, lines 21-26, at page 165, lines 27-33, and at page 168, lines 17-23. Support for the amendment to Claim 140 can be found, for example, in Claim 99 as originally filed and in the specification at page 60, lines 18-23. Support for the amendment to Claim 141 can be found, for example, in Claim 100 as originally filed and in the specification at page 60, lines 25-29. Support for the amendment to Claim 143 can be found, for example, in Claim 103 as originally filed and in the specification at page 163, line 31 to page 164, line 4. Support for the amendment to Claim 145 can be found, for example, in Claim 113 as originally filed and in the specification at page 166, lines 11-17. Support for the amendment to Claim 148 can be found, for example, in Claim 111 as originally filed and in the specification at page 165, lines 27-33.

Further support for the amendments to Claims 122-124, 126-131, 134, 136-141, 143, 145 and 148 are provided in Claims 122-124, 126-131, 134, 136-141, 143, 145 and 148 as presented in the amendment and response filed November 14, 2003. Claims 122-124, 126-131, 134, 136-141, 143, 145 and 148 were entered in to the record of the present application without objection in the Office Action mailed March 10, 2004, indicating that the PTO considered this amendment to be fully supported by the application as filed.

Applicants note that Claims 122, 124, 126, 127, 130-131, 134 and 137 recite groups of secondary mutations that are smaller than the groups of secondary mutations recited by the claims as originally filed. For example, Claim 122 as amended recites a reduced group of secondary mutations in comparison to Claim 122 as originally filed. Although the groups of secondary mutations are reduced in number, each member of each group of secondary mutations presented by the new claims is recited in a single group by the specification and at least one claim. Thus, the reduced groups of secondary mutations recited by Claims 122, 124, 126, 127, 130-131, 134 and 137 are supported by the larger sets of secondary mutations described in the application as originally filed.

In support of Applicants' contention that the larger groups of secondary mutations recited by the as-filed claims provide adequate description for the claims presented in the instant amendment, Applicants respectfully invite the PTO's attention to M.P.E.P.

§ 2173.05(i). Here, the M.P.E.P. explains that "[i]f alternative elements are positively recited in the specification, they may be explicitly excluded in the claims." See M.P.E.P.

§ 2173.05(i). The legal basis for this rule is found in *In re Johnson* 558 F.2d 1008, 194 U.S.P.Q. 187 (C.C.P.A., 1977). In *In re Johnson*, the Applicants described a genus of chemical compounds in the application as filed, then claimed a subgenus of the compounds

that lacked word-for-word support in the application as filed. The Court of Customs and Patent Appeals held that “the specification, having described the whole [genus], necessarily described the [subgenus] remaining.” *See In re Johnson* 558 F.2d 1008, 1019, 194 U.S.P.Q. 187, 196 (C.C.P.A., 1977). Thus, Applicants respectfully submit that *In re Johnson* and M.P.E.P. § 2173.05(i) show that the larger groups of secondary mutations described by the application as filed support the smaller groups of secondary mutations recited by Claims 127-138 as presented in the instant amendment.

In view of the foregoing, Applicants submit that the amendments to Claims 122-124, 126-131, 134, 136-141, 143, 145 and 148, do not present any new matter, and are proper in that they are believed to place the claims in condition for allowance. Accordingly, Applicants respectfully request the entry and consideration of the amendment to the claims pursuant to 37 C.F.R. § 1.116.

**C. New Claims 151-211**

Claims 151-211 have been added. New Claims 151-211 are fully supported by the specification and claims of the application as originally filed.

In particular, support for new Claims 151-155 can be found, for example, in Claims 98 and 100 as originally filed and in the specification at page 60, lines 1-17 and lines 25-29, and at page 94, lines 26-32. Support for new Claims 156-160 can be found, for example, in Claim 98 as originally filed and in the specification at page 60, lines 1-17, and at page 94, lines 26-32. Support for new Claims 161-165 can be found, for example, in Claims 98, 103, and 106 as originally filed and in the specification at page 60, lines 1-17, and page 94, lines 26-32.

Support for new Claims 166-173 can be found, for example, in Claims 98 and 100 as originally filed and in the specification at page 60, lines 1-17 and lines 25-29, and at page 94, lines 26-32. Support for new Claim 174 can be found, for example, in Claim 99 as originally filed and in the specification at page 60, lines 18-23. Support for new Claim 175 can be found, for example, in Claim 107 as originally filed and at page 164, line 28 to page 165, line 3. Support for new Claim 176 can be found, for example, in Claim 109 as originally filed and in the specification at page 165, lines 11-15 and page 189, Table 27. Support for new Claim 177 can be found, for example, in Claim 117 as originally filed and in the specification at page 167, lines 11-28, and at page 94, lines 26-32.

Support for new Claims 178-186 can be found, for example, in Claim 98 as originally filed and in the specification at page 60, lines 1-17, and at page 94, lines 26-32. Support for new Claim 187 can be found, for example, in Claim 99 as originally filed and in the

specification at page 60, lines 18-23. Support for new Claim 188 can be found, for example, in Claim 100 as originally filed and in the specification at page 60, lines 25-29. Support for new Claim 189 can be found, for example, in Claim 101 as originally filed and in the specification at page 163, lines 2-19. Support for new Claim 190 can be found, for example, in Claim 102 as originally filed and in the specification at page 163, lines 21-29. Support for the amendment to Claim 191 can be found, for example, in Claim 104 as originally filed and in the specification at page 164, lines 7-11. Support for the amendment to Claim 192 can be found, for example, in Claim 105 as originally filed and in the specification at page 164, lines 13-19. Support for new Claim 193 can be found, for example, in Claim 107 as originally filed and in the specification at page 164, line 28, to page 165, line 3. Support for new Claim 194 can be found, for example, in Claim 109 as originally filed and in the specification at page 165, lines 11-15. Support for new Claim 195 can be found, for example, in Claim 110 as originally filed and in the specification at page 165, lines 17-25. Support for new Claim 196 can be found, for example, in Claim 112 as originally filed and in the specification at page 166, lines 1-10. Support for new Claim 197 can be found, for example, in Claim 117 as originally filed and in the specification at page 167, lines 11-28, and at page 94, lines 26-32.

Support for new Claims 198-205 can be found, for example, in Claims 98, 103, and 106 as originally filed and in the specification at page 60, lines 1-17, and page 94, lines 26-32. Support for new Claim 206 can be found, for example, in Claim 99 as originally filed and in the specification at page 60, lines 18-23. Support for new Claim 207 can be found, for example, in Claim 100 as originally filed and in the specification at page 60, lines 25-29. Support for new Claim 208 can be found, for example, in Claim 103 as originally filed and in the specification at page 163, line 31 to page 164, line 4. Support for new Claim 209 can be found, for example, in Claim 106 as originally filed and in the specification at page 164, lines 21-26. Support for new Claim 210 can be found, for example, in Claim 109 as originally filed and in the specification at page 165, lines 11-15. Support for new Claim 211 can be found, for example, in Claim 111 as originally filed and in the specification at page 165, lines 27-33.

In view of the foregoing, Applicants submit that new Claims 151-211 are fully supported by the specification and claims of the application as originally filed. Accordingly, no new matter is introduced by the instant amendment. Therefore, Applicants hereby respectfully request entry of the present amendment under 37 C.F.R. § 1.116.

Applicants believe that the present amendment is suitable for entry under 37 C.F.R. § 1.116 because it places the claims in condition for allowance and because no new

search would be required to examine the subject matter of the present claims. Accordingly, Applicants earnestly that the present amendment be entered into the record of the present application.

**III. The Rejection of Claims 122-150 under 35 U.S.C. § 112, Second Paragraph, Should Be Withdrawn**

Claims 122-150 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite on several bases. Applicants respectfully submit that the rejection of these claims is moot in view of the amendments to or cancellation of the claims presented in the present response.

**A. The Legal Standard**

Under 35 U.S.C. § 112, second paragraph, a claim must particularly point out and distinctly claim the subject matter which the applicant regard as his invention. *See* 35 U.S.C. § 112, second paragraph. This statutory mandate is met when “one skilled in the art would understand the bounds of the claim when read in light of the specification.” *See Solomon v. Kimberly-Clark Corporation*, 216 F.3d 1372, 1378, 55 USPQ2d 1279, 1282 (Fed. Cir., 2000), quoting *Personalized Media Communications, LLC v. International Trade Commission et al.*, 161 F.3d 696, 705, 48 USPQ2d 1880, 1888 (Fed. Cir., 1998). “If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more.” *See Personalized Media*, 161 F.3d at 705, 48 USPQ2d at 1888, quoting *Miles Lab., Inc. v. Shandon, Inc.* 997 F.2d 870, 238 USPQ2d 1123 (Fed. Cir., 1993).

**B. The Rejection of Claims 122-150 Should be Withdrawn**

Applicants respectfully submit that a skilled artisan can readily understand the scope of Claims 122-141, 143, 145 and 147-148 as amended in the present response, and therefore these claims are not indefinite under 35 U.S.C. § 112, second paragraph.

First, the PTO contends that the steps of Claims 122, 126, 127, 138, 139, and 149, directed to methods for assessing the effectiveness of protease antiretroviral therapy, do not have a clear point that ties to the effectiveness of the antiretroviral therapy. Applicants respectfully submit that the rejection is moot in view of the cancellation of Claim 149 and amendments to Claims 122, 126, 127, 138 and 139. Further, Applicants respectfully submit that one of skill in the art can understand the scope of amended Claims 122, 126, 127, 138, and 139. Therefore, Claims 122, 126, 127, 138, and 139 are not indefinite under 35 U.S.C. § 112, second paragraph.

Second, the PTO alleges that the subject matter claimed in Claims 131-137 as previously pending conflicts with the subject matter claimed in Claims 139-149. Specifically, the PTO argues that Claims 131-137 state that certain mutations result in a decrease in susceptibility to saquinavir and/or indinavir, while Claims 139-149 state that the same mutations indicate an increase in susceptibility to saquinavir and/or indinavir.

Without acquiescing to the propriety of this rejection, Applicants have cancelled Claims 132, 133 and 149 solely to advance prosecution of the instant claims. Thus, Applicants respectfully submit that the rejection of Claims 132, 133 and 149 as being indefinite under 35 U.S.C. § 112, second paragraph, is moot in view of cancellation of these claims.

Moreover, Applicants respectfully submit that Claims 131 and 134-137, and Claims 139-141, 143, 145, and 147-148 are not directed to conflicting subject matter. Contrary to the PTO's assertion, Claims 131 and 134-137 do not recite the same specific combinations of mutations as Claims 139-141, 143, 145, and 147-148. For example, Claim 131, recites, *inter alia*, that the presence of a mutation at codon 82 and a secondary mutation at a codon selected from the group consisting of codons 23, 53, and 33 indicates a decrease in susceptibility to saquinavir. The specification teaches that the combinations of mutations recited in Claim 131 are correlated with decreased susceptibility to saquinavir (*see* specification, page 174, lines 2-6 and lines 22-25, Table 15, rows 7, Table 16, rows 4, 6 and 7).

In contrast, Claim 143, recites, *inter alia*, that the presence of a mutation at codon 82 and a secondary mutation at codon 32 or codon 39 indicates an increase in susceptibility to saquinavir and detecting. The specification teaches that the presence of such combinations of mutations are correlated with increased susceptibility to saquinavir (*see* specification, page 174, lines 6-11 and lines 25-31, Table 16, rows 19-20).

None of the combinations of mutations recited by Claim 143 overlap those recited by Claim 131. For example, Claim 143 does not recite detecting a mutation at codon 82 and a secondary mutation at codons 23, 53 or 33, which are recited in Claim 131. Thus, Claim 131 and Claim 143 recite different combinations of mutations. Therefore, although Claim 131 recites, *inter alia*, a decrease in susceptibility to saquinavir and Claim 143 recites, *inter alia*, an increase in susceptibility to saquinavir, Claim 131 and Claim 143 are not directed to conflicting subject matter.

Likewise, Claim 137 and 145 are not directed to conflicting subject matter, since they also recite different combinations of mutations. Claim 137 recites, *inter alia*, that the presence of a mutation at codon 82 and a secondary mutation at a codon selected from the

group consisting of codons 55 and 53 indicates a decrease in susceptibility to indinavir. In contrast, Claim 145 recites, *inter alia*, that the presence of a mutation at codon 82 and a secondary mutation at codon 13 indicates an increase in susceptibility to indinavir. Again, none of the combinations of mutations recited by Claim 137 is recited by Claim 145. Thus, Claim 137 and 145 are not directed to conflicting subject matter, because they do not recite the same specific combination of mutations. Accordingly, Applicants submit that Claims 131 and 134-137 and Claims 139-141, 143, 145, and 147-148 are not directed to conflicting subject matter and therefore are not indefinite under 35 U.S.C. § 112, second paragraph.

Third, the PTO asserts that Claims 125, 130-134, 136, 137, and 143-145 recite terms that lack antecedent basis. Without acquiescing to the propriety of this rejection, Applicants have amended Claims 124, 128, 129, 131 and 141 such that antecedent basis for each term in the rejected claims is found in the claim from which the rejected claims directly depend. Applicants respectfully submit that each of terms recited by amended Claims 125, 130-131, 134, 136, 137 and 143-145 can be found in the claims from which they depend. Therefore, there is sufficient antecedent basis for each of the terms recited by Claims 125, 130-131, 134, 136, 137 and 143-145 in view of these amendments. Applicants note for the record that these amendments do not change the scope of the claims, and certainly do not constitute a narrowing of the claimed subject matter, but merely clarify that which Applicants have always regarded as their invention. Accordingly, Applicants submit that Claims 25, 130-131, 134, 136, 137 and 143-145 are not indefinite under 35 U.S.C. § 112, second paragraph.

Fourth, the PTO contends that the nexus between expression of the indicator gene and activity of the HIV protease as recited by Claim 150 is not clear. Without acquiescing to the propriety of this rejection, Applicants have cancelled Claim 150 without prejudice. Applicants respectfully submit that the rejection of Claim 150 is therefore moot in view of the cancellation of Claim 150.

In view of the foregoing, Applicants respectfully submit that amended Claims 122-131, 134-141, 143, 145, and 147-148 are not indefinite under 35 U.S.C. § 112, second paragraph, and that the rejection of Claims 132, 133, 142, 144, 146 and 149-150 is moot in view of the cancellation of these claims. Thus, Applicants respectfully request that the rejection of Claims 122-150 under 35 U.S.C. § 112, second paragraph, be withdrawn.

#### **IV. The Rejection of Claims 122-126 under 35 U.S.C. § 102(b)**

Claims 122-126 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Craig *et al.*, 1998, *AIDS*. 12:1611-1618 (“Craig”). Without acquiescing to the



propriety of the rejection and solely to expedite the prosecution of the instant claims, Applicant have amended Claims 122, 124 and 126. Applicants respectfully submit that *Craig* does not teach each and every element of Claims 122-126 as amended and thus the rejection of these claims being anticipated by *Craig* is moot. Accordingly, Applicants respectfully request the rejection of Claims 122-126 under 35 U.S.C. § 102(b) be withdrawn.

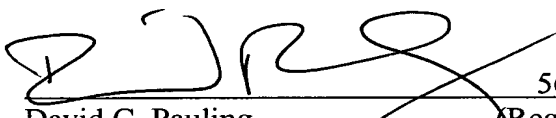
### **CONCLUSION**

In light of the above amendments and remarks, Applicants respectfully submit that Claims 122-131, 134-141, 143, 145, 147-148 and 151-211 satisfy all the criteria for patentability and are in condition for allowance. Accordingly, Applicants respectfully request that the Examiner reconsider this application with a view towards allowance and solicit an expeditious passage of Claims 122-131, 134-141, 143, 145, 147-148 and 151-211 to issuance. The Examiner is invited to call the undersigned attorney at (650) 730-3939, if a telephone call could help resolve any remaining items.

Pursuant to 37 CFR § 1.136(a)(3), the Commissioner is authorized to charge all required fees, fees under 37 CFR § 1.17 and all required extension of time fees, or credit any overpayment, to Jones Day U.S. Deposit Account No. 50-3013 (order no. 101962-999032).

Respectfully submitted,

Date: March 2, 2005

  
56,056  
David C. Pauling (Reg. No.)  
For: Nikolaos C. George (Reg. No. 39,201)  
**JONES DAY**  
222 East 41<sup>st</sup> Street  
New York, NY 10017  
(212) 326-3939